

1           ORTHOPEDIC FIXATION SYSTEM INCLUDING PLATE ELEMENT  
2                   WITH THREADED HOLES HAVING DIVERGENT AXES  
3

4           This application is a continuation-in-part of U.S. Serial No. 10/315,787, filed Dec. 10,  
5 2002, which is a continuation-in-part of U.S. Serial No. 10/159,611, filed May 30, 2002,  
6 which is a continuation-in-part of U.S. Serial No. 09/735,228, filed Dec. 12, 2000 and now  
7 issued as U.S. Pat. No. 6,440,135, which is a continuation-in-part of U.S. Serial No.  
8 09/524,058, filed March 13, 2000 and now issued as U.S. Pat. No. 6,364,882, and U.S. Serial  
9 No. 09/495,854, filed Feb. 1, 2000 and now issued as U.S. Pat. No. 6,358,250, all of which  
10 are hereby incorporated by reference herein in their entireties.  
11

12                           BACKGROUND OF THE INVENTION  
13

14   1. Field of the Invention

15           This invention relates broadly to surgical devices. More particularly, this invention  
16 relates to a bone fixation system including a plate element and an arrangement of pegs fixed  
17 relative to the plate element.  
18

19   2. State of the Art

20           Referring to Fig. 1, a Colles' fracture is a fracture resulting from compressive forces  
21 being placed on the distal radius 10, and which causes backward displacement of the distal  
22 fragment 12 and radial deviation of the hand at the wrist 14. Often, a Colles' fracture will  
23 result in multiple bone fragments 16, 18, 20 which are movable and out of alignment relative

1 to each other. If not properly treated, such fractures result in permanent wrist deformity. It is  
2 therefore important to align the fracture and fixate the bones relative to each other so that  
3 proper healing may occur.

4  
5 Alignment and fixation are typically performed by one of several methods: casting,  
6 external fixation, interosseous wiring, and plating. Casting is non-invasive, but may not be  
7 able to maintain alignment of the fracture where many bone fragments exist. Therefore, as  
8 an alternative, external fixators may be used. External fixators utilize a method known as  
9 ligamentotaxis, which provides distraction forces across the joint and permits the fracture to  
10 be aligned based upon the tension placed on the surrounding ligaments. However, while  
11 external fixators can maintain the position of the wrist bones, it may nevertheless be difficult  
12 in certain fractures to first provide the bones in proper alignment. In addition, external  
13 fixators are often not suitable for fractures resulting in multiple bone fragments. Interosseous  
14 wiring is an invasive procedure whereby screws are positioned into the various fragments  
15 and the screws are then wired together as bracing. This is a difficult and time consuming  
16 procedure. Moreover, unless the bracing is quite complex, the fracture may not be properly  
17 stabilized. Plating utilizes a stabilizing metal plate typically against the dorsal side of the  
18 bones, and a set of parallel pins extending from the plate into holes drilled in the bone  
19 fragments to provide stabilized fixation of the fragments. However, the currently available  
20 plate systems fail to provide desirable alignment and stabilization. Likewise, other fractures  
21 at the ends of other long bones suffer from similar problems.

22

## SUMMARY OF THE INVENTION

It is therefore an object of the invention to provide an improved fixation and alignment system for fractures at the end of long bones and which can specifically be used to treat fractures at the end of long bones.

It is another object of the invention to provide a fixation system which desirably aligns and stabilizes multiple bone fragments in a fracture to permit proper healing.

In accord with these objects, which will be discussed in detail below, a fixation system is provided which generally includes a plate intended to be positioned against the bone, a plurality of bone screws for securing the plate along a non-fractured portion of the bone, and a plurality of pegs (fasteners having threaded heads and threaded or non-threaded shafts) which extend from the plate and into bone fragments of the fracture.

According to one embodiment, the plate is generally a T-shaped plate defining an elongate shaft portion, a head portion angled relative to the shaft portion, a first side which is intended to contact the bone, and a second side opposite the first side. The shaft portion includes a plurality of countersunk screw holes for the extension of the bone screws therethrough. The head portion includes a plurality of threaded peg holes for receiving the pegs therethrough. According to a first embodiment, the peg holes are preferably arranged along a curve. According to a second embodiment, the peg holes are preferably linearly arranged. In either embodiment, the peg holes are preferably positioned increasingly distal in

1 a medial to lateral direction along the second side. According to a preferred aspect of the  
2 invention, axes through the peg holes are oblique relative to each other, and are preferably  
3 angled relative to each other in two dimensions.

4  
5 In use for stabilization of Colles' fracture, the plate is positioned with its first side  
6 against the volar side of the radius and bone screws are inserted through the bone screw holes  
7 into the radius to secure the plate to the radius. The bone fragments are aligned and a drill is  
8 used to drill holes into the bone fragments in alignment with the axes of the peg holes. The  
9 pegs are then inserted through the peg holes and into the holes in the bone, and the heads of  
10 the pegs are threadably engaged in the head portion of the plate. The pegs define a support  
11 framework which is preferably divergent both medial and laterally such that the pegs are  
12 arranged to follow the contour of subchondral bone of the bone being stabilized. The  
13 fixation system thereby secures the bone fragments in their proper orientation.

14  
15 According to another embodiment, a fixation system includes a device having a  
16 proximal shaft portion defining an intramedullary nail and relatively flat plate head portion,  
17 preferably horizontally and vertically offset relative to the shaft portion by a neck portion.  
18 The shaft portion includes screw holes, and the plate portion has a low, narrow profile and  
19 includes longitudinally displaced peg holes, each of which is adapted to orient a peg in a  
20 different orientation from the others.

21  
22 In use, a relatively small incision is made in the skin, and the shaft portion is  
23 introduced through the incision and through the fracture location into the medullary canal of

1 the bone, and the plate portion of the device is maneuvered against a surface of the bone at  
2 the metaphysis. The shaft portion is fixed relative to the bone with one or more screws,  
3 while pegs are inserted through holes drilled in alignment with the peg holes and define a  
4 framework for stabilization and support of subchondral bone fragments. Moreover, as the  
5 pegs preferably enter the subchondral fragments from a plurality of directions, additional  
6 fixation of the device into the bone is provided.

7  
8 The fixation system can be adapted to treatment of fractures at multiple sites. For  
9 example, the distal radius, the proximal humerus, the distal femur, the proximal tibia, the  
10 distal tibia, and the hip are all suitable for application of the system of the invention.

11  
12 Additional objects and advantages of the invention will become apparent to those  
13 skilled in the art upon reference to the detailed description taken in conjunction with the  
14 provided figures.

#### 15 16 BRIEF DESCRIPTION OF THE DRAWINGS

17  
18 Fig. 1 is an illustration of an extremity subject to a Colles' fracture;  
19

20 Fig. 2 is a top volar view of a fixation system specifically adapted for a distal radius  
21 fracture according to a first embodiment of the invention;  
22

1            Fig. 3 is a side view of a peg with a non-threaded shaft according to an embodiment  
2 of the fixation system of the invention;

3

4            Fig. 3a is a side view of a peg with a threaded shaft according to an embodiment of  
5 the fixation system of the invention;

6

7            Fig. 4 is a side view of a bone screw of an embodiment of the fixation system of the  
8 invention;

9

10           Fig. 5 is a side view of an embodiment of the fixation system of the invention;

11

12           Fig. 6 is a front end view of an embodiment of the volar fixation system of an  
13 embodiment of the invention;

14

15           Fig. 7 is an exploded side view of the right hand volar plate and guide plate according  
16 to the first embodiment of the fixation system of the invention;

17

18           Fig. 8 is a side view of the guide plate positioned on the right hand volar plate to  
19 provide drill guide paths in accord with the invention;

20

21           Fig. 9 is an illustration of the first embodiment of the volar fixation system provided  
22 in situ aligning and stabilizing a Colles' fracture;

23

1            Fig. 10 is a top volar view of a left hand volar fixation system according to the second  
2            embodiment of the invention;

3  
4            Fig. 11 is a lateral side view of the left hand volar fixation system according to the  
5            second embodiment of the invention;

6  
7            Fig. 12 is a bottom view of the left hand volar fixation system according to the second  
8            embodiment of the invention;

9  
10           Fig. 13 is an enlarged side elevation of a bone peg according to the second  
11           embodiment of the volar fixation system of the invention;

12  
13           Fig. 14 is a proximal end view of the bone peg of Fig. 13;

14  
15           Fig. 15 is first partial top view of the head portion of the left hand volar plate  
16           according to the second embodiment of the volar fixation system of the invention;

17  
18           Figs. 16-19 are section views across line 16-16, 17-17, 18-18, and 19-19, respectively  
19           in Fig. 15;

20  
21           Fig. 20 is second partial top view of the head portion of the left hand volar plate  
22           according to the second embodiment of the volar fixation system of the invention;

1 Figs. 21-24 are section views across line 21-21, 22-22, 23-23, and 24-24, respectively  
2 in Fig. 20;

3

4 Fig. 25 is a broken partial longitudinal section view across a distal end of a third  
5 embodiment of the volar fixation system of the invention;

6

7 Fig. 26 is a proximal perspective view of a bone peg according to the third  
8 embodiment of the invention;

9

10 Figs. 27 and 28 are proximal and distal perspective views, respectively, of a set screw  
11 according to the third embodiment of the invention;

12

13 Fig. 29 is a distal end top perspective view of a fourth embodiment of a fixation  
14 device of the invention;

15

16 Fig. 30 is a proximal end top perspective view of the fixation device of Fig. 29;

17

18 Fig. 31 is a distal end bottom perspective view of the fixation device of Fig. 29;

19

20 Fig. 32 is a broken top view of the fixation device of Fig. 29; and

21

22 Fig. 33 is a broken longitudinal section view taken along line 33-33 in Fig. 32.

23



## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Turning now to Figs. 2 through 4, a first embodiment of a fixation system 100 for aligning and stabilizing multiple bone fragments in a Colles' fracture generally includes a substantially rigid T-shaped plate 102 intended to be positioned against the volar side of the radial bone, a plurality of preferably self-tapping bone screws 104 for securing the plate 102 along a non-fractured portion of the radial bone, and a plurality of bone pegs 108, 108a which extend from the plate 102 and into bone fragments of a Colles' fracture.

Referring to Figs. 2, 5 and 6, more particularly, the T-shaped plate 102 defines a relatively flat head portion 116 angled upwards relative to an elongate relatively flat shaft portion 118, a first side 120 which is intended to contact the bone, and a second side 122 opposite the first side. As the head portion and shaft portion are angled relative to each other, the first side preferably generally defines two planar portions. The angle  $\phi$  between the head portion 116 and the shaft portion 118 is preferably approximately  $18^\circ$  and bent at a radius of approximately 1.00 inch (Fig. 5). The distal edge 121 of the head portion 116 is preferably angled proximally toward the medial side at an angle  $\alpha$ , e.g.,  $5^\circ$ , relative to a line P, which is perpendicular to the shaft portion. In one embodiment, the head portion 116 preferably has a width of 0.913 inch and a greatest proximal-distal dimension (i.e., from the corner of angle  $\alpha$  to the shaft portion) of approximately 0.69 inch, and the shaft portion preferably has a width of 0.375 inch and a length of 1.40 inches, though alternative dimensions may be provided for plates adapted for various individuals, or for plates adapted for use on bones other than the radius. The plate 102 preferably has a thickness of at least

1 approximately 0.098 inch. The plate 102 is preferably made from a titanium alloy, such as  
2 Ti-6A-4V.

3  
4 The shaft portion 118 includes three preferably countersunk screw holes 124, 126,  
5 128 for the extension of the bone screws 104 therethrough. One of the screw holes, 128, is  
6 preferably generally elliptical (or oval).

7  
8 The head portion 116 includes four threaded peg holes 130, 132, 134, 136 for  
9 individually receiving the pegs 108, 108a therethrough. According to a first preferred aspect  
10 of the first embodiment of the invention, the peg holes 130, 132, 134, 136, each preferably  
11 0.100 inch in diameter, are preferably substantially linearly arranged along the head portion  
12 116, and are provided such that the adjacent peg holes are provided further distally in a  
13 medial to lateral direction along the second side. Alternatively, the peg holes may be  
14 arranged along a smooth curve such as a shallow parabolic curve.

15  
16 The peg holes define axes  $A_1$ ,  $A_2$ ,  $A_3$ ,  $A_4$  which are oblique (not parallel) relative to  
17 each other, and more preferably are angled in two dimensions (medial/lateral and  
18 proximal/distal) relative to each other; i.e., the pegs once inserted into the peg holes are also  
19 angled in two dimensions relative to each other. More particularly, the first axis  $A_1$  of the  
20 first peg hole 130 (that is, the most proximal and medial peg hole) is preferably directed  
21 normal to the first side 120 of the head portion 116. The axis  $A_2$  of the adjacent peg hole  
22 132, i.e., the second axis, is preferably angled approximately 1-7° distal and lateral relative to  
23 the first axis  $A_1$ , and more preferably approximately 2.5° distal and lateral relative to the first

1 axis A<sub>1</sub>. The axis A<sub>3</sub> of the peg hole 134 laterally adjacent the second peg hole 132, i.e., the  
2 third axis, is preferably angled approximately 7-13° distal and lateral relative to the first axis  
3 A<sub>1</sub>, and more preferably approximately 10° distal and lateral relative to the first axis A<sub>1</sub>. The  
4 axis A<sub>4</sub> of the peg hole 134 laterally adjacent the third peg hole 132, i.e., the fourth axis, is  
5 preferably angled approximately 10-30° distal and lateral relative to the first axis A<sub>1</sub>, and  
6 more preferably approximately 20° distal and lateral relative to the first axis A<sub>1</sub>. The second  
7 side of the head portion 116, distal of the peg holes 130, 132, 134, 136 is preferably beveled.  
8

9 Referring back to Figs. 3 and 3a, the pegs 108, 108a, preferably approximately 0.872  
10 inch in length, each have a threaded head 138 adapted to threadably engage the threads about  
11 the threaded peg holes 130, 132, 134, 136. Such dimensions permit the pegs to adequately  
12 support the bone fragments such that the bone is able to heal correctly. The pegs may have a  
13 relatively smooth shaft 140 (Fig. 3) or a threaded shaft (Fig. 3a). If threaded, the shafts 140a  
14 are preferably threaded at a pitch different from the threads on the head 138 of the pegs 108a.  
15 The pegs 108 are also preferably made from titanium alloy, and may be coated in a ceramic,  
16 e.g., titanium nitride, to provide a bone interface which will not adversely affect bone  
17 healing.  
18

19 Turning now to Figs. 7 and 8, the system 100 may also include a guide plate 146  
20 which temporarily sits on the second side 122 of the volar plate 102 and includes guide holes  
21 148, 150, 152, 154 (illustrated in overlapping section in Fig. 8) oriented according to the axes  
22 A<sub>1</sub>, A<sub>2</sub>, A<sub>3</sub>, A<sub>4</sub> of the peg holes for guiding a drill into the bone fragments at the required  
23 orientation. That is, the guide holes together with the peg holes define a drill guide path

1 along the axes with sufficient depth to accurately guide a drill (not shown) to drill holes at  
2 the desired pin orientations. The volar plate 102 and guide plate 146 are also preferably  
3 provided with mating elements, such as a plurality of holes 156, 158 on the second side of  
4 the volar plate (Fig. 2), and a plurality of protuberances 160 on the mating side of the guide  
5 plate (Fig. 7), to temporarily stabilize the guide plate on the volar plate during the hole  
6 drilling process. Alternatively, a threaded drill guide or other guide means may be used to  
7 guide a drill to drill holes in appropriate orientations relative to the peg hole axes, as is  
8 known in the art.

9  
10 Referring to Figs. 2 through 9, in use, the volar plate 102 is positioned with its first  
11 side 120 against the volar side of the radius. Bone screws 104 (either self-tapping or inserted  
12 with the aid of pre-drilled pilot holes) are inserted through the bone screw holes 124, 126,  
13 128 into the radius bone 10 to secure the volar plate 102 to the radius. The bone fragments  
14 16, 18, 20 are then aligned with the radius 10. Next, the guide plate 146 is positioned on the  
15 second side of the volar plate. A drill, guided by a guide path formed by the peg holes and  
16 the guide holes, drills holes into and between the bone fragments 16, 18, 20 (and possibly  
17 also a portion of the integral radius, depending upon the particular location and extent of the  
18 fracture), and the guide plate is then removed. The pegs 108, 108a (any combination thereof  
19 including solely non-threaded shaft pegs 108 and solely threaded shaft pegs 108a) are then  
20 inserted through the peg holes 130, 132, 134, 136 and into the holes drilled into the  
21 fragments, and the heads of the pegs are threadably engaged in the volar plate. The pegs 108,  
22 108a, extending through the oblique-axis peg holes 130, 132, 134, 136, are positioned  
23 immediately below the subchondral bone of the radius and support the bone fragments for

1 proper healing. The volar fixation system thereby secures the bone fragments in their proper  
2 orientation.

3  
4 Referring to Figs. 10-12, a second embodiment of a volar plate 210, substantially  
5 similar to the first embodiment (with like parts having numbers incremented by 100) and  
6 used in substantially the same manner as the first embodiment is shown. The plate 210  
7 preferably has a length of approximately 2.35 inches, which is approximately 0.35 inch  
8 greater than in the first embodiment. This additional length accommodates an extra bone  
9 screw hole 229 in the shaft portion of the volar plate such that the volar plate preferably  
10 includes four bone screw holes 224, 226, 228, 229. The additional bone screw in screw hole  
11 229 increases plate stability over the three holes of the first embodiment. The plate 210  
12 preferably tapers in thickness from the shaft portion 218 to the head portion 216. A preferred  
13 taper provides a proximal shaft portion 218 thickness of approximately .098 inch and head  
14 portion 216 thickness of approximately .078 inch. The taper decreases the thickness of the  
15 head portion 216 relative to the shaft portion such that the weight of the volar plate is  
16 reduced and an improved tendon clearance is provided. The distal edge of the head portion  
17 216 has an increased taper (preferably approximately 60° relative to a line normal to the  
18 head) to a distal edge 221. The edge 221 is broken (i.e., made blunt) to prevent irritation or  
19 disturbance to the surrounding anatomy.

20  
21 The head portion 216 includes four threaded peg holes 230, 232, 234, 236 for  
22 individually receiving pegs 208 therethrough (Figs. 13 and 14), and a guide hole 256 for  
23 alignment of a guide plate. According to a preferred aspect of the second embodiment of the

1 invention, the peg holes 230, 232, 234, 236, preferably 0.100 inch in diameter, are preferably  
2 linearly arranged along the head portion 216, and are provided such that the adjacent peg  
3 holes are provided further distally in a medial to lateral direction along the first and second  
4 sides. Referring to Fig. 15, more particularly, according to a preferred dimensions of the  
5 second embodiment of the invention, the center of peg hole 230 is located approximately  
6 0.321 inch proximal line P and approximately 0.750 inch medial of the lateral edge 237 of  
7 the head portion, the center of peg hole 232 is located approximately 0.306 inch proximal  
8 line P and 0.557 inch medial of the lateral edge 237, the center of peg hole 234 is located  
9 approximately 0.289 inch proximal line P and approximately 0.364 inch medial of the lateral  
10 edge 237, and the center of peg hole 236 is located approximately 0.272 inch proximal line P  
11 and approximately 0.171 inch medial of the lateral edge 237. As such, the distance from  
12 each of the peg holes to the distal edge 221 of the volar plate is relatively greater than in the  
13 first embodiment, and provides a preferred alignment with respect to the tapered distal edge  
14 221.

15  
16 Referring to Figs. 15-24, in addition, as in the first embodiment, the peg holes define  
17 axes  $A_1$ ,  $A_2$ ,  $A_3$ ,  $A_4$  which are oblique relative to each other, and more preferably are angled  
18 in two dimensions (medial/lateral and proximal/distal) relative to each other; i.e., the pegs  
19 208 once inserted into the peg holes are also angled in two dimensions relative to each other.  
20 More particularly, as in the first embodiment, the first axis  $A_1$  of the first peg hole 230 is  
21 preferably directed normal (Figs. 16 and 21) to the first side 220 of the head portion 216.  
22 The axis  $A_2$  of peg hole 232 is preferably angled approximately 1-7° distal (Fig. 17) and  
23 approximately 1-7° lateral (Fig. 22) relative to the axis  $A_1$ , and more preferably

1 approximately 2.5° both distal and lateral relative to axis A<sub>1</sub>. The axis A<sub>3</sub> of peg hole 234 is  
2 preferably angled approximately 7-13° distal (Fig. 18) and approximately 7-13° lateral (Fig.  
3 23) relative to axis A<sub>1</sub>, and more preferably approximately 10° both distal and lateral relative  
4 to axis A<sub>1</sub>. Axis A<sub>4</sub> of the peg hole 234 is preferably angled approximately 10-30° distal  
5 (Fig. 19) and approximately 10-30° lateral (Fig. 24) relative to axis A<sub>1</sub>, and more preferably  
6 approximately 20° both distal and lateral relative to axis A<sub>1</sub>.

7  
8 Referring to Figs. 13 and 16-19, each of the peg holes has a countersunk portion 270,  
9 272, 274, 276, respectively, for receiving the head 238 of peg 208. Countersunk portions  
10 270, 272 are each preferably approximately .030 inch deep and threaded according to the  
11 head of the pegs, as described below. Countersunk portion 274 is preferably approximately  
12 .042 inch deep and likewise threaded. Countersunk portion 276 is preferably approximately  
13 0.056 inch deep and also threaded. The respective depths of the countersunk portions are  
14 adapted to better accommodate the heads 238 of the pegs 208 relative to the respective axes  
15 of the peg holes.

16  
17 Referring to Figs. 13 and 14, the pegs 208, preferably approximately 0.872 inch in  
18 length, each have a threaded head 238 adapted to threadably engage threads about the peg  
19 holes 230, 232, 234, 236 and cylindrical shaft 240 which may be threaded or non-threaded.  
20 The heads 238 preferably include a no. 5 thread 280 at a count of 44 per inch. In addition,  
21 the heads 238 are rounded and include a hex socket 282 to facilitate stabilized threading into  
22 the peg holes. This design accommodates the reduced thickness of the volar plate at the head  
23 portion 216. The shafts 240 are preferably approximately 0.0792 inch (2 mm) in diameter

1 and 0.765 inch in length. Such dimensions permit the pegs to adequately support the bone  
2 fragments such that the bone is able to heal correctly. The pegs 208 are also preferably made  
3 from titanium alloy, and are preferably 'tiodized' to provide a strong finish which does not  
4 adversely affect bone healing.

5

6 From the foregoing embodiments, it is appreciated that the peg holes define a  
7 plurality of axes at least two of which are oblique relative to each other and at least one of  
8 which is oblique relative to the lower surface of the head of the plate immediately  
9 surrounding such hole. In addition, the threaded peg holes define axes which diverge in a  
10 direction away from the lower surface of the plate. As such, pegs coupled within such holes  
11 define a support framework which is preferably divergent both medial and laterally such that  
12 the pegs are arranged to follow the contour of subchondral bone of the bone being stabilized.

13

14 Furthermore, the head portion provides substantial support structure both proximal  
15 and distal of the threaded holes for supporting the bone fragments. So that substantial  
16 surface structure of the plate is provided for the support, preferably the peg holes define less  
17 than fifty percent of the area of the head portion, as clearly shown in Figs. 2 and 15.  
18 Furthermore, as also shown in the embodiment of Fig. 15, a greater area of the head portion  
19 is preferably provided distal of the arrangement of the peg holes (on the side of the pegs  
20 holes opposite the shaft portion) relative to the area on the head portion proximal of the  
21 arrangement of peg holes (on the portion of the head portion adjacent the shaft portion). This  
22 large distal area provides a buttress for supporting bone fragments thereunder.

23



Turning now to Fig. 25, a volar fixation system 300 according to a third embodiment is shown in which each peg can be articulated through a range of angles within a respective peg hole and fixed at a desired angle within the range. The system includes a volar plate 302, four pegs 308, and four set screws 310, as well as bone screws, not shown but described above, for mounting the volar plate to the radius.

The volar plate 310 is substantially similar to the first or second embodiments, with the exception of the shape of the peg holes described below, and is used in substantially the same manner as the first embodiment. Each peg hole 312 in the volar plate includes a cylindrical upper bore 314 provided with threads 316 and a lower portion 318 having a radius of curvature. The surface 320 of the lower portion and/or the surface 330 of the head of the peg is preferably roughened, e.g., by electrical, mechanical, or chemical abrasion, or by the application of a coating or material having a high coefficient of friction. The lower opening 322 of each peg hole includes a circumferential bevel 324.

Referring to Figs. 25 and 26, each peg 308 includes a head 330 and a cylindrical shaft 332. The proximal portion 334 of the head 330 includes a cup 336 having an outer radius  $R_o$  substantially corresponding to the radius of the lower portion 318 of the peg holes 312, and a relatively smaller inner radius  $R_i$  of curvature. The head 330 defines preferably approximately  $160^\circ$  of a sphere. The shaft 332 includes a slight taper 336 at the intersection with the head 330, and a rounded distal end 338. According to a preferred manufacture of the pegs 308, the cylindrical shaft 332 is first provided with a sphere (not shown) or a hemisphere (not shown) at a proximal end. If a sphere is provided, it is cut to a hemisphere.

1 The hemisphere is then hollowed and further reduced to the 160° shape. Finally, the taper  
2 336 is provided at the intersection.

3

4 Turning now to Figs. 25, 27 and 28, each set screw 310 includes a proximal hex  
5 socket 340, circumferential threads 342 adapted to engage the threads 316 of the upper bore  
6 314 of the peg hole, and distal hemispherical portion 344 having substantially the same  
7 radius of curvature as the inner radius of curvature of the cup 336, and preferably  
8 substantially smaller than a radius of the peg holes 312.

9

10 In accord with the third embodiment, the volar plate is positioned on the radius, a  
11 hole is drilled through the elliptical screw hole on the volar plate and into the radius. A bone  
12 screw is inserted through the plate and into the bone. The fractured bones are adjusted under  
13 the plate into their desired stabilized positions, and the bone screw is tightened. Then,  
14 through the peg holes, the surgeon drills holes into the bone for the stabilization pegs. Unlike  
15 the previous embodiments, the holes may be drilled at any angle within a predefined range,  
16 and preferably at any angle within a range of 20° relative to an axis normal  $A_N$  to the lower  
17 surface of the head of the volar plate. Each hole may be drilled at the same angle or at  
18 relatively different angles. After each hole is drilled, a peg 308 is inserted therein. The bevel  
19 324 at the lower end 322 of the peg hole 312 and the taper 336 on the shaft cooperate to  
20 permit the peg to be oriented with greater angularity relative to the axis  $A_N$ , if required, as  
21 interference between the peg hole and peg shaft is thereby reduced. Once the peg 308 has  
22 been appropriately positioned within the peg hole, one of the set screws 310 is threaded into  
23 the upper bore 314 of the peg hole 312. The hemispherical portion 344 contacts the head 330

1 of the peg, seating in the concavity of the cup 336. As the set screw 310 is tightened, the  
2 head of the peg, which may be roughened, is sandwiched between the set screw and the  
3 roughened inner surface of the lower portion of the peg hole, thereby securing the peg in the  
4 selected orientation. The other pegs are similarly positioned and angularly fixed.

5  
6 Turning now to Figs. 29 through 33, a fixation device 410 for the treatment of a  
7 fracture at an end of a long bone, i.e., a metaphyseal fracture, is provided. The device 410 is  
8 preferably made of metal, e.g., titanium or stainless steel, and includes an intramedullary nail  
9 shaft portion 412 and a plate-like head portion 414 that is preferably horizontally and  
10 vertically offset relative to the shaft portion at a neck portion (or transition zone) 16. As  
11 such, the shaft portion 412 and the head portion 414 are fixed in a parallel, but non-coaxial  
12 relationship, with the head portion 414 longitudinally displaced relative to the shaft portion  
13 412.

14  
15 The shaft portion 412 is preferably substantially circular in cross section and includes  
16 a tapered resilient (flexible) section 420, and a relatively rigid section 422 generally  
17 substantially larger in diameter adjacent the shoulder portion 416. The rigid section 422  
18 preferably tapers toward and into the resilient section 420. Referring to Figs. 32 and 33, the  
19 rigid section 422 of the shaft portion 412 preferably includes two optionally threaded screw  
20 holes 424, 426 preferably extending vertically through the diameter of the shaft portion 412  
21 and longitudinally displaced along the length of the rigid section 422. The screw holes 424,  
22 426, if threaded are adapted to receive machine screws as described in detail in co-pending  
23 U.S. Serial No. 10/315,787, and if not threaded are adapted to receive cortical screws, as

1 described in detail in co-pending U.S. Serial No. 10/159,611, both of which are hereby  
2 incorporated by reference herein in their entireties.

3  
4 With respect to Figs. 29 through 33, the plate-like head portion 414 is substantially  
5 rigid and has a low and narrow profile. The head portion 414 has a slightly concave bottom  
6 surface 444 (adapting the head portion to the anatomy) and a slightly convex upper surface  
7 446 (reducing potential irritation of tendons and other tissue). The concave and convex  
8 surfaces 444 and 446 may be defined by facets approximating curved surfaces. The head  
9 portion 414 also includes preferably three longitudinally displaced, threaded peg holes 450,  
10 452, 454, each of which is preferably adapted to orient a respective peg (e.g., pegs 108 and  
11 108a of Figs. 3 and 3a) in a different orientation from the others; i.e., the axes of the peg  
12 holes are oblique relative to each other so that the pegs inserted therethrough diverge away  
13 from the bottom surface 444 and define a framework under the subchondral surface which  
14 supports the fracture. In use, the shaft portion 412 of the device 410 is inserted in the  
15 intramedullary canal and the plate-like head portion 414 is provided external of the bone, as  
16 described in detail in previously incorporated U.S. Serial Nos. 10/315,787 and 10/159,611.

17  
18 There have been described and illustrated herein embodiments of an orthopedic  
19 fixation system suitable for numerous applications related to the fixation of various bone  
20 fractures. While embodiments of the invention have been described, it is not intended that  
21 the invention be limited thereto, as it is intended that the invention be as broad in scope as the  
22 art will allow and that the specification be read likewise. Thus, while in one embodiment a  
23 volar plate for fixation of a fracture at the distal radius has been shown and described, it is

1 appreciated that a plate with divergent threaded peg holes may be optimized in shape and  
2 size for placement on the dorsal radius or for fractures of other bones, such as of the ulna,  
3 humerus, femur, tibia, fibula, adjacent the ankle joint, etc. Furthermore, while particular  
4 materials for the elements of the system have been disclosed, it will be appreciated that other  
5 materials may be used as well. In addition, fewer or more peg holes and pegs than shown  
6 may be used, preferably such that at least two pegs angled in two dimensions relative to each  
7 other are provided. Also, while a right-handed volar plate for the distal radius is described  
8 with respect to an embodiment of the invention, it will be appreciated that both right- and  
9 left-handed models are intended, with such alternate models being mirror images of each  
10 other. Also, the plate, nail-plate device, and pegs may be provided in different sizes adapted  
11 for implant into different size people. It will therefore be appreciated by those skilled in the  
12 art that yet other modifications could be made to the provided invention without deviating  
13 from its spirit and scope as claimed.